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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/650,055	08/29/2000	Robert A. Kay	1040-5	8753

23869 7590 09/17/2002

HOFFMANN & BARON, LLP  
6900 JERICHO TURNPIKE  
SYOSSET, NY 11791

EXAMINER
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JONES, DWAYNE C

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/650,055

**Applicant(s)**

KAY ET AL.

**Examiner**

Dwayne C Jones

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1-48 are pending.
2. Claims 1-48 are rejected.

### ***Information Disclosure Statement***

3. The information disclosure statement filed on January 16, 2001 has been reviewed and considered, see enclosed copy of PTO FORM 1449.

### ***Drawings***

4. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murch et al. of U.S. Patent No. 6,046,179. Murch et al. teach of a time-released composition of N-acetylglucosamine with cellulose or hydrophilic polymers, (see abstract and columns 2 and 3). Although the prior art reference of Murch et al. is directed to N-acetylglucosamine vice glucosamine, it would have been obvious to the skilled artisan to easily obtain a sustained-release composition of glucosamine, in view of Murch et al., by easily removing the acetyl group from position No. 2 of the glucose moiety.

8. Claims 1-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson et al. of U.S. Patent No. 5,364,845 in view of Shell of U.S. Patent No. 5,582,837 in further view of McClain et al. Henderson teaches of the administration of glucosamine for treatment, prevention and repair of connective tissue, namely arthritis, joint inflammation, (see column 1, lines 15-23 and column 4, lines 28-29, and claims 1-18). Shell discloses of sustained-release oral dosages forms that contain an active agent that is dispersed in alkyl cellulose, such as hydroxyethylcellulose or hydroxypropylcellulose, (see abstract and claims 1 and 2). In addition, Shell provides motivation to the skilled artisan to administer pharmaceuticals and nutraceuticals to (1) reduce side effects from the pharmaceutical and (2) to administer the pharmaceutical less frequently, (see column 3). McClain et al. teach that glucose is an important regulator of cell growth and metabolism and that adverse effects of hyperglycemia are

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reflections of normal regulation by abnormal concentrations of glucose. McClain et al. also teach that the hexosamine biosynthesis pathway regulates the uptake of glucose, synthesis of glycogen and glycolysis. McClain et al. also disclose that excess hexosamine flux causes resistance to insulin, (see abstract and entire article). The determination of a dosage and modes of administration, which have the optimum therapeutic index is well within the purview of the skilled artisan. Accordingly, the artisan would be motivated to determine optimum amounts and modes of administration in order to get the maximum effect of the drug. In addition, Shell provides motivation to the skilled artisan to administer pharmaceuticals and nutraceuticals to (1) reduce side effects from the pharmaceutical and (2) to administer the pharmaceutical less frequently, (see column 3). For these reasons, the administration of the nutraceutical of glucosamine could be administered and a sustained-release method so that the hexosamine biosynthesis pathway is not compromised. These prior art references provide the skilled artisan with the necessary motivation to control hyperglycemia and insulin resistance with the manipulation of the hexosamine biosynthesis pathway via the controlled administration of glucosamine.

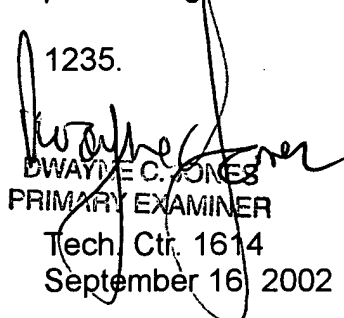
Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.

  
DWAYNE C. JONES  
PRIMARY EXAMINER

Tech. Ctr. 1614  
September 16 2002